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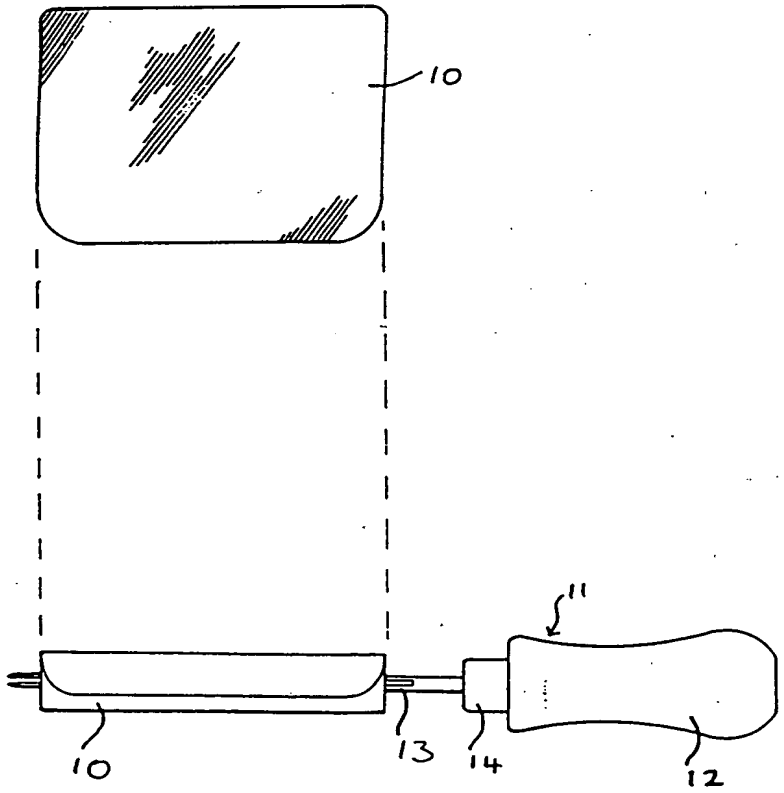
With international search report.

(54) Title: SELF EXPANDING VASCULAR ENDOPROSTHESIS FOR ANEURYSMS

(57) Abstract

A self expanding vascular endoprosthesis for aneurysms comprising a sheet of a resiliently flexible biocompatible material, such as polypropylene which sheet has been rolled upon itself about one of its longitudinal edges. The tightly rolled endoprosthesis is introduced in the end of the catheter through a contiguous artery into the artery having the aneurysm. After ejection from the catheter at a suitable point in the artery the endoprosthesis expands to form a bridge isolating the aneurysm from the arterial blood flow. The endoprosthesis stimulates cellular proliferation in the adjacent vascular tissue which assists in forming a seal between the endoprosthesis and the vascular tissue. The resultant endothelial growth also assists in maintaining the endoprosthesis in position in the artery.



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+ DESIGNATIONS OF "SU"

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"Self Expanding Vascular Endoprosthesis for Aneurysms"

Field of the Invention

The present invention relates to a self expanding vascular endoprosthesis for aneurysms and to apparatus and a method for introducing such an endoprosthesis into an artery.

Background Art

An Aneurysm is the focal abnormal dilation of an artery. The complication which arise from aneurysms are specifically rupture, embolisation, fistularisation and symptoms related to pressure on surrounding structures. Aneurysms are commonly found in the abdominal aorta, being that part of the aorta which extends from the diaphragm to the point at which the aorta bifurcates into the common iliac arteries. These abdominal aortic aneurysms typically occur between the point at which the renal arteries branch from the aorta and the bifurcation of the aorta.

The standard treatment for aneurysms is to resect them by opening the aneurysm directly and inserting an inlaid graft mode of a biocompatible material such as Dacron. The operation in most cases is large entailing considerable blood loss, at least 10 day hospital and a mortality of about 5% in elective cases. This mortality is normally related to associated vascular problems such as myocardial infarction. Many patients cannot be submitted to such a large procedure because of intercurrent disease and therefore die of the aneurysm or the complications thereof.

It has been proposed by Balka et al., (Journal of Surgical Research 40 305-309 (1986)) to treat abdominal aortic aneurysms by the insertion of an intraluminal prosthesis, which approximates the diameter of the aorta above and below the aneurysm, into the aorta through the common femoral artery. In this case the prosthesis comprised a polyurethane tube with a nitinol and/or

stainless steel frame which was designed in such a configuration that it could be compressed inside a catheter and then regain its original shape after being discharged into the aorta. This proposal does not appear to have been adapted for the treatment of humans due to difficulty in ensuring that the prosthesis would expand sufficiently to form a seal with the aorta above and below the aneurysm. The present inventor has developed a prosthesis which provides an alternative to that proposed by Balka et al.

In a first aspect the present invention consists in a self expanding vascular endoprosthesis for aneurysms comprising a substantially imperforate sheet of a resiliently flexible biocompatible material, the sheet being rolled upon itself about one of its longitudinal edges.

In a second aspect the present invention consists in apparatus for introducing a self expanding vascular endoprosthesis for aneurysms into an artery, comprising an elongate tubular catheter, a self expanding vascular prosthesis for aneurysms according to the present invention disposed within the catheter and means for ejecting the endoprosthesis from the catheter.

In a third aspect the present invention consists in a method for introducing an expanding vascular endoprosthesis into an artery having an aneurysm comprising the steps of:

inserting one end of a catheter containing a self expanding vascular endoprosthesis for aneurysms according to this invention into an artery communicating with the artery having the aneurysm, moving the catheter along the patient's vascular system until the end of the catheter is adjacent the aneurysm, ejecting the endoprosthesis from the one end of the catheter such that it bridges across

the aneurysm and expands into contact with the artery above and below the aneurysm and withdrawing the catheter from the patient.

The endoprosthesis is preferably formed from a substantially rectangular sheet of a suitable grade of polypropylene or another similar synthetic plastics material. The sheet preferably has a thickness of from 0.01mm to 0.8mm, more preferably 0.3mm to 0.5mm. The corners of the sheet which are on the outside of the prosthesis are preferably rounded to avoid ulceration of the arterial wall. The length of the sheet must be sufficient to bridge the aneurysm but is preferably sufficient that one end rests against a bifurcation of the artery in which the aneurysm occur. This latter preferment assists in retention of the endoprosthesis in a position in which it bridges over the aneurysm.

The width of the sheet is preferably from 1.75 to 2.5 times the circumference of the artery above and below the aneurysm, 1.75 to 2.5 times the circumference of the larger of them. This width will ensure that when the prosthesis expands within the artery there will still be sufficient overlap between the edges of the endoprosthesis to form a substantial seal inhibiting blood from flowing out of the prosthesis into the aneurysm. In some special cases it may be desirable for the sheet to have a width less than the circumference of the artery into which it is to be placed. Such cases occur where blood vessels diverge from the artery containing the aneurysm. In these cases it is necessary to preserve the blood supply to these diverging vessels and the endoprosthesis may have a width such that after it has expanded it bears sealingly against the arterial wall on either side of the diverging blood vessel. If the aneurysm is on the side of the artery distal to the diverging blood vessel the endoprosthesis can in this way bridge the aneurysm while

still allowing blood supply to the diverging vessels.

In another embodiment of the invention the endoprosthesis is such that upon release from the end of the catheter it is capable of increasing in length as well as expanding radially outwardly. The sheet forming the endoprosthesis might have a "memory" causing it to want to expand from its rolled up cylindrical form into a helical form of greater diameter than the initial cylinder and of greater length. The overlapping coils of the expanded helical coil serving to prevent fluid communication between the interior of the endoprosthesis and the aneurismal sac. In another form of the invention the sheet forming endoprosthesis may be of a very thin film having ribs which assume a helical form when released from the endoprosthesis. The advantage of an endoprosthesis which can increase in length after release from the catheter is that it is easier to thread a catheter containing such a shortened endoprosthesis through the patient's vascular system to the point of the aneurysm.

The sheet of material from which the endoprosthesis is rolled up preferably has a compliance mismatch with the vascular tissue and is preferably quite stiff in a longitudinal direction. This is believed to have the effect of stimulating a reaction in the arterial wall and thereby inducing cellular proliferation in the vascular tissue surrounding the ends of the endoprosthesis. This causes a proliferation of endothelial cells which has the effect of adhering the endoprosthesis to the arterial wall. The endoprosthesis thus has a self suturing effect which retains it against movement along the artery.

The material from which the endoprosthesis is formed should be resiliently flexible so that upon being released from the constraint of the catheter the prosthesis will expand to bear against the arterial wall above and below the aneurysm. The use of the sheet of material rolled up

along one of its side edges to form a scroll has been found to allow the prosthesis to expand very considerably if need be. This feature is important because the neck of the aneurysms tend to vary greatly between patients. Also depending upon where the ends of the endoprosthesis extend to the size of the native artery may be quite small or quite large. It is important that the endoprosthesis does not occlude vessels extending laterally from the artery and thus it may be necessary to terminate the endoprosthesis in a mildly distended part of the aneurysm. For this reason it may be necessary for the endoprosthesis to expand not merely to the normal diameter of the artery but to whatever extent is necessary to form a seal with the artery at either end of the aneurysm so that systalic blood pressure is not transmitted to the aneurysmal sac formed between the endoprosthesis and the distended arterial wall.

In the case of the abdominal aorta the normal internal diameter of the aorta is about 18mm. Abdominal aortic aneurysms will typically have a diameter of from 40 to 70mm. The abdominal aorta between the renal arteries and the iliac arterial bifurcation is typically about 110mm. The aneurysm normally extends along a substantial portion of the abdominal aorta and is bounded at either end by a neck of undistended arterial wall adjacent the renal arteries and adjacent the iliac arterial bifurcation. In this case then the prosthesis is preferably rolled up from a sheet of polypropylene having a thickness of 0.4mm, a length of 110mm and a width of from 98mm to 142mm. It should be recognized however that the neck of the aneurysms tend to be very variable and it may be necessary to use a sheet wider than that indicated to form the endoprosthesis.

The present inventor has found that the endoprosthesis according to the present invention may be

rolled up to a very small diameter allowing its introduction into a deep artery, such as the abdominal aorta, from a more superficial but much smaller artery, such as the common femoral artery.

The apparatus according to the present invention comprises a conventional catheter into which the endoprosthesis has been inserted in a rolled up condition and means to eject the endoprosthesis from an end of the catheter. The apparatus may also include a guide wire and/or sensing means to assist in the determination of the correct position at which the endoprosthesis should be ejected from the catheter. The ejection of the endoprosthesis from the catheter may be achieved by holding the catheter stationary and pushing the endoprosthesis from it using a plunger extending down the catheter or the plunger may be abutted against the proximal end of the endoprosthesis and the catheter withdrawn from around the endoprosthesis.

Brief Description of the Drawings

Hereinafter given by way of example is a preferred embodiment of the present invention described with reference to the accompanying drawings in which:-

Fig. 1 is a front elevational view of a sheet of material suitable for forming into a self expanding vascular endoprosthesis according to this invention;

Fig. 2 is a perspective view of the sheet of Fig. 1 which has been rolled into the form of a self expanding vascular endoprosthesis according to this invention on a suitable forming tool;

Fig. 3 is a longitudinal sectional view of a catheter containing a self expanding vascular endoprosthesis according to this invention and a device for ejecting the prosthesis from the catheter;

Fig. 4 is a diagrammatic ventral view of a patient showing a vascular endoprosthesis according to the

invention in position spanning an abdominal aorta aneurysm;

Fig. 5 is a cross-sectional view along V-V of Fig. 4;

Fig. 6 is a cross-sectional view along VI-VI of Fig. 4; and

Fig. 7 is a cross-sectional view of a self expanding vascular endoprosthesis according to the present invention in a position in the thoracic aorta of a patient.

Best Method

The sheet 10 of Fig. 1 is formed of surgical grade, imperforate polypropylene having a thickness of 0.4mm, a width of 120mm and a length of 110mm with rounded corners. The sheet 10 is preferably rolled up into a self expanding vascular endoprosthesis on a tool 11 having a handle 12 and, extending axially from it, a bifurcated rod 13. A sleeve 14 is slidable disposed on the rod 13. In use one side edge of the sheet 10 is slid between the bifurcation of the rod 13 and the tool 12 rotated to roll the sheet 10 about the rod 13. After being tightly rolled onto the rod 13 the sheet 10, now formed into an endoprosthesis, is inserted into the proximal end of a suitable catheter 15. The tool 12 can then be disengaged from the endoprosthesis 10 by positioning the collar 14 against the end of the endoprosthesis 10 and withdrawing the rod 13 from within the rolled up endoprosthesis 10. The endoprosthesis 10 is now ready for insertion into a patient.

Fig. 4 shows a typical abdominal aortic aneurysm into which an endoprosthesis 10 has been inserted. The abdominal aorta 16 has become distended to from an aneurysm 17 between the renal arteries 17 and the point at which the aorta 16 bifurcates to form the left and right iliac arteries 19. The endoprosthesis 10 is introduced to bridge the aneurysm 17 between a neck 21 adjacent the renal arteries 18 and a neck 22 adjacent the iliac arteries 19. This introduction is achieved by giving the

patient a local anaesthetic in the region of one of the common femoral arteries 23 and introducing the catheter 15 through that artery and through the contiguous iliac artery into the aorta 16. The position of the tip of the catheter 15 relative to the renal arteries 18 needs to be known accurately to prevent the endoprosthesis 10 being introduced into the aorta 16 at a level where its upper end will occlude the renal arteries or where its lower end will expand in one of the iliac arteries 19. This is achieved in a manner known per se by angiography or by the introduction of an endoscope or some other form of inter-luminal or transcutaneous imaging system (not shown) through the catheter 15.

After the tip of the catheter 15 has been correctly positioned in the aorta 16 the endoprosthesis is ejected from the catheter 15 into the aorta 16. This is preferably achieved by positioning an ejector 24 in the catheter 15 with an end portion 25, which forms a close sliding fit with the catheter 15, abutting against the end of the endoprosthesis 10. The catheter 15 is then carefully withdrawn. As it is ejected from the catheter 15 is natural resilience of the endoprosthesis 10 causes it to expand until it bears firmly against the aorta 16 at its narrowest points, in this case the neck portions 21 and 22 (see Fig. 5). The expanded endoprosthesis 10 will form a tube bridging the aneurysm 17 to form an aneurysmal sac between the endoprosthesis 10 and the aorta 16 in the region of the aneurysm 17 which is not in fluid communication with the arterial blood flow (see Fig. 6).

It is believed that the stiffness of the synthetic plastics material from which the endoprosthesis 10 is formed will induce cellular proliferation in the aortal wall adjacent the ends of the endoprosthesis 10. This cellular proliferation assists in holding the

endoprosthesis 10 in place in the aorta 16.

As is seen in Fig. 7, if it is desired to preserve blood flow from an artery 26, such as the thoracic aorta, into a diverging blood vessel 27, such as the spinal artery, an endoprosthesis 28 may be introduced into the artery 26 which has a width less than the circumference of the artery. In this case the isolation of the aneurysm from the arterial blood flow relies upon the endoprosthesis forming a seal with the inside of the artery 26 on either side of the diverging blood vessels 27.

It can be seen from the foregoing that the use of the endoprosthesis according to this invention, and the method according to this invention can dramatically simplify the treatment of aneurysms. It also allows treatment of patients with concurrent disease states which would not otherwise be amendable to treatment at all.

CLAIMS:-

1. A self expanding vascular endoprosthesis for aneurysms comprising a substantially imperforate sheet of a resiliently flexible biocompatible material, the sheet being rolled upon itself about one of its longitudinal edges.

2. An endoprosthesis as claimed in claim 1 in which the endoprosthesis is formed from a sheet of polypropylene or another similar synthetic plastics material.

3. An endoprosthesis as claimed in claim 2 in which the endoprosthesis is formed from a sheet of polypropylene having a thickness of from 0.01 to 0.8mm.

4. An endoprosthesis as claimed in claim 3 in which the endoprosthesis is formed from a sheet of polypropylene having a thickness of from 0.3 to 0.5mm.

5. An endoprosthesis as claimed in any one of claims 1 to 4 in which the sheet has a width 1.75 to 2.5 times the circumference of the artery into which the endoprosthesis is to be introduced above or below the aneurysm.

6. Apparatus for introducing a self expanding vascular endoprosthesis for aneurysms into an artery, comprising an elongate tubular catheter, a self expanding vascular prosthesis for aneurysms according to any one of claims 1 to 5 disposed within the catheter and means for ejecting the endoprosthesis from the catheter.

7. A method for introducing an expanding vascular endoprosthesis into an artery having an aneurysm comprising the steps of:

inserting one end of a catheter containing a self expanding vascular endoprosthesis for aneurysms according to any one of claims 1 to 5 into an artery communicating with the artery having the aneurysm, moving the catheter along the patient's vascular system until the end of the catheter is adjacent the aneurysm, ejecting the endoprosthesis from the one end of the catheter such that

it bridges across the aneurysm and expands into contact with the artery above and below the aneurysm and withdrawing the catheter from the patient.

8. A method as claimed in claim 7 in which the endoprosthesis is ejected from the catheter by inserting an abutment means into the catheter to abut against an end of the endoprosthesis and withdrawing the catheter while maintaining the abutment means stationary.

9. A method as claimed in claim 7 in which the catheter is inserted into the common femoral artery and the endoprosthesis is ejected into the abdominal aorta.

10. A method as claimed in claim 7 in which the apparatus additionally includes sensing means adapted to sense or indicate the position of the catheter in an artery.

INTERNATIONAL SEARCH REPORT

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent classification (IPC) or to both National Classification and IPC

Int. Cl.[5] A61F 2/06, A61M 29/00, 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC	A61F 2/06, 1/24, A61M 25/00, 29/00, 29/02, 29/04

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category*	Citation of Document, [11] with indication, where appropriate of the relevant passages [12]	Relevant to Claim No [13]
X	JP,A,64-86983 (NIPPON ZEON CO LTD) 31 March 1989 (31.03.89) See Figs 1, 2, 7B	(1-6)
Y		(7-10)
X	JP,A,57-89859 (Toshiba Cor p) 4 June 1982 (04.06.82) See Fig 3(a)	(1)
Y		(2-10)
X	AU,A,14904/88 (Terumo Kabashiki Kaisha) 6 October 1988 (06.10.88) See Fig 2(a), page 9 lines 11-14	(1)
Y		(2-10)
P, X	JP,A,2-255157 (Nippon Zeon KK) 15 October 1990 (15.10.90) See Figs 2(a), 5	(1-6)
	(continued)	

* Special categories of cited documents : [10]

"A" Document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
2 October 1991 (02.10.91)	10 October 91
International Searching Authority	**Signature of Authorized Officer**
AUSTRALIAN PATENT OFFICE	A.R. HENDRICKSON

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y	US,A,4740207 (Kreamer) 26 April 1988 (26.04.88)	(1-10)
Y	US,A,4923464 (DiPira Jr) 8 May 1990 (08.05.90)	(7-10)
Y	US,A,4830003 (Wolff et al) 16 May 1989 (16.05.89) See Figs 7-8, Col 4 line 64 - Col 5 line 15	(6-10)
Y	US,A,4820298 (Leveen & Leveen) 11 April 1989 (11.04.89) See Col 2 lines 39-56	(6-10)

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim numbers , because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim numbers , because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4a

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL APPLICATION NO. PCT/AU 91/00326

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
AU	8814904	EP 411118 WO 8807390	JP 63238872	US 5037427	
US	4740207				
US	4923468	EP 402825	JP 3026250		
US	4830003	EP 346564	JP 2167178		
US	4820298				

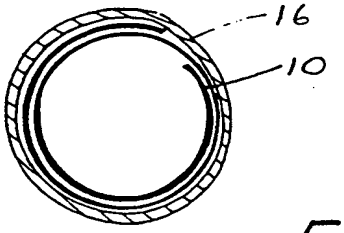

FIG. 5

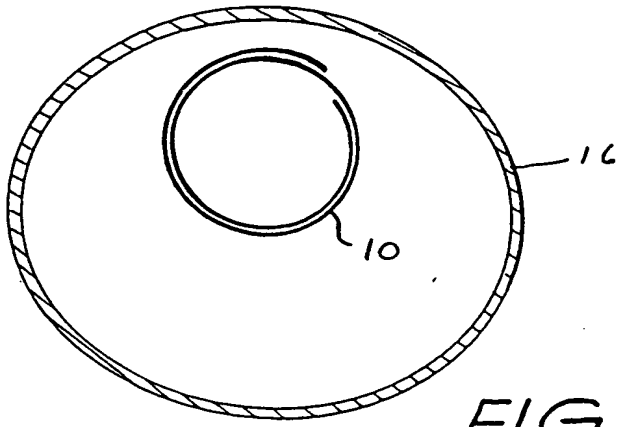

FIG. 6

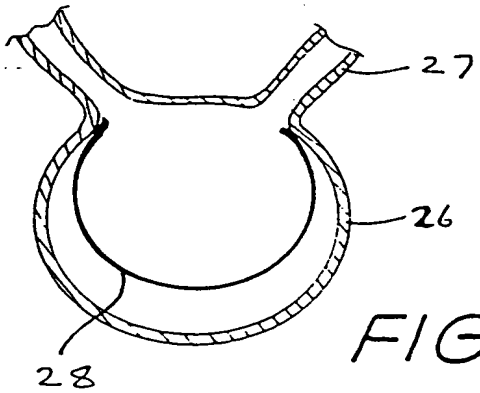

FIG. 7

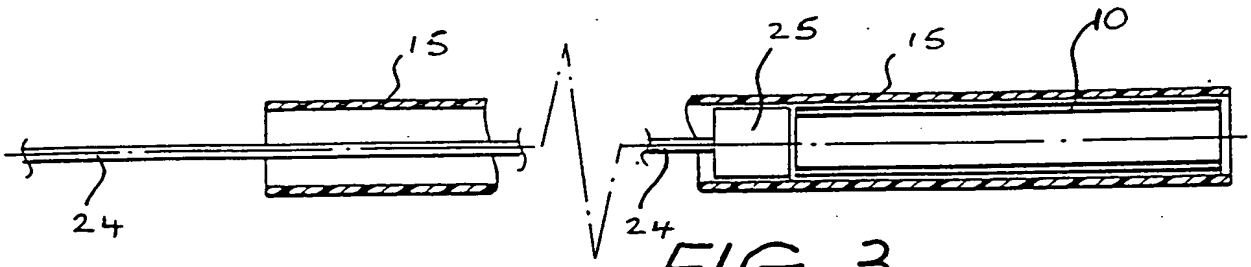

FIG. 3

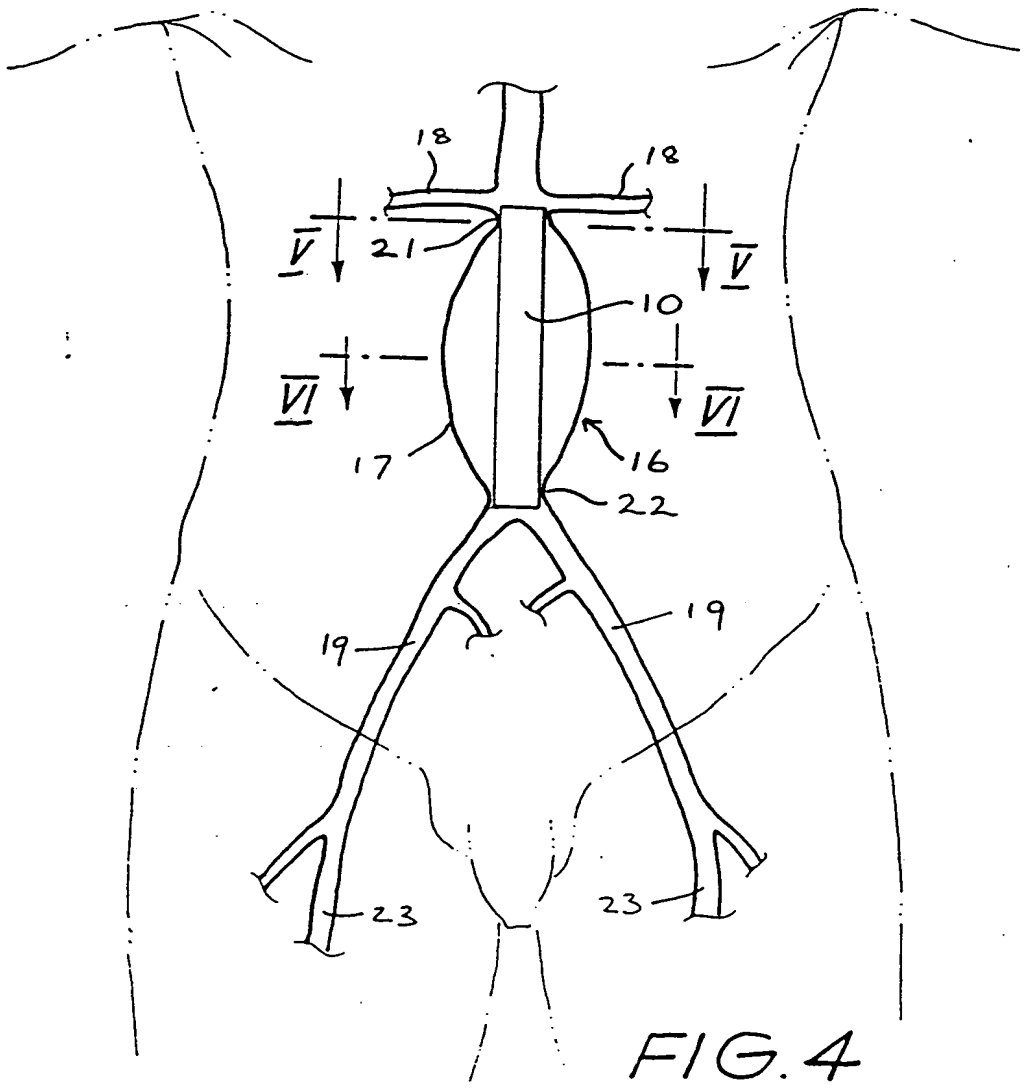

FIG. 4

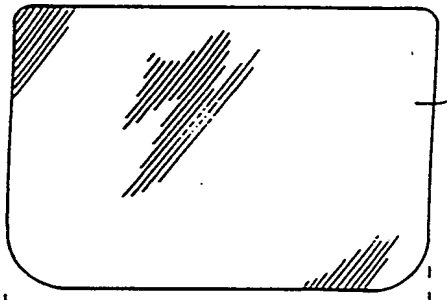

FIG. 1

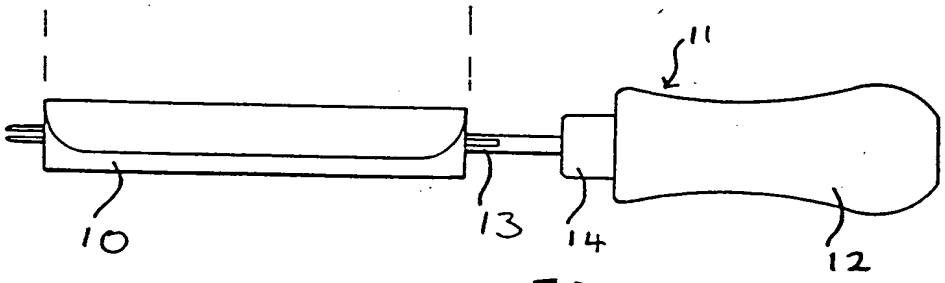

FIG. 2